

Filed: July 25, 2001

Sub 1
a1
~~1. (Amended) A pharmaceutical composition which comprises orlistat and a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex.~~

Sub 2
a2
~~2. (Amended) The composition according to claim 1, wherein pharmaceutically acceptable bile acid sequestrant is selected from the group consisting of β -cyclodextrin and γ -cyclodextrin.~~

Sub 3
a3
~~3. (Amended) A pharmaceutical composition which comprises orlistat and a pharmaceutically acceptable acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colestesvelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin.~~

Sub 4
a4
~~4. (Amended) The composition according to claim 1, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant.~~

~~5. (Amended) The composition according to claim 1, which comprises:~~
(a) from about 5 to about 1000 mg of orlistat;
(b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex;
(c) from about 0.1 to about 10 g of a filler;
(d) from about 0.05 to about 3.0 g of a surfactant;
(e) from about 0.05 to about 2.0 g of a disintegrant;

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- (f) from about 0.02 to about 2.0 g of a binder;
 - (g) from about 0.001 to about 1.0 g of a lubricant;
 - (h) from about 0.1 to about 5.0 g of a flowability enhancer;
 - (i) from about 0.01 to about 4.0 g of a sweetener; and
 - (j) and about 0.001 to about 0.5 g of a colorant.

Sub B1
27. (Amended) A kit for use in the treatment of obesity, which comprises (a) a first component which is orlistat and (b) a second component which is a bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, present in oral unit dosage form.

28. (Amended) A method of treating obesity in an obese patient, which comprises administering to a patient in need of such treatment (a) a therapeutically effective amount of orlistat and (b) a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex in an amount effective to reduce gastrointestinal side effects associated with the lipase inhibitor.

Sub B1
32. (Amended) A method of reducing the gastrointestinal side effects associated with orlistat treatment, which comprises administering to a patient being treated with orlistat an amount of a bile salt sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-

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94 cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, effective to reduce the side effects associated with the orlistat treatment. \rightarrow

Sub B \rightarrow 25 33. (New) The composition according to claim 10, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant. --

- 26 34. (New) The composition according to claim 33, which comprises:
- (a) from about 5 to about 1000 mg of orlistat;
 - (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin;
 - (c) from about 0.1 to about 10 g of a filler;
 - (d) from about 0.05 to about 3.0 g of a surfactant;
 - (e) from about 0.05 to about 2.0 g of a disintegrant;
 - (f) from about 0.02 to about 2.0 g of a binder;
 - (g) from about 0.001 to about 1.0 g of a lubricant;
 - (h) from about 0.1 to about 5.0 g of a flowability enhancer;
 - (i) from about 0.01 to about 4.0 g of a sweetener; and
 - (j) and about 0.001 to about 0.5 g of a colorant. \rightarrow

27 35. (New) The composition according to claim 13, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant. \rightarrow

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- ²⁸~~36~~ (New) The composition according to claim ²⁷~~35~~, which comprises:
- (a) from about 5 to about 1000 mg of orlistat;
 - (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin;
 - (c) from about 0.1 to about 10 g of a filler;
 - (d) from about 0.05 to about 3.0 g of a surfactant;
 - (e) from about 0.05 to about 2.0 g of a disintegrant;
 - (f) from about 0.02 to about 2.0 g of a binder;
 - (g) from about 0.001 to about 1.0 g of a lubricant;
 - (h) from about 0.1 to about 5.0 g of a flowability enhancer;
 - (i) from about 0.01 to about 4.0 g of a sweetener; and
 - (j) and about 0.001 to about 0.5 g of a colorant. --
- ²⁹~~37~~. (New) The compositions according to claim ²⁵~~33~~, wherein the orlistat is present in an amount of from about 10 to about 500 mg. --
- ³⁰~~38~~. (New) The composition according to claim ²⁹~~37~~, wherein the orlistat is present in an amount of about 120 mg. --
- ³¹~~39~~. (New) The composition according to claim ²⁵~~33~~, wherein the orlistat is present in an amount of from about 20 to about 100 mg. --
- ³²~~40~~. (New) The composition according to claim ³¹~~39~~, wherein the orlistat is present in an amount of about 60 mg. --

- ³³~~41~~ (New) The composition according to claim ²⁵~~33~~, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g. --
- ³⁴~~42~~ (New) The composition according to claim ³³~~41~~, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g. --
- ³⁵~~43~~ (New) The compositions according to claim ²⁷~~35~~, wherein the orlistat is present in an amount of from about 10 to about 500 mg. --
- ³⁶~~44~~ (New) The composition according to claim ³⁵~~43~~, wherein the orlistat is present in an amount of about 120 mg. --
- ³⁷~~45~~ (New) The composition according to claim ³⁵~~43~~, wherein the orlistat is present in an amount of from about 20 to about 100 mg. --
- ³⁸~~46~~ (New) The composition according to claim ³⁷~~45~~, wherein the orlistat is present in an amount of about 60 mg. --
- ³⁹~~47~~ (New) The composition according to claim ²⁷~~35~~, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g. --
- ⁴⁰~~48~~ (New) The composition according to claim ³⁹~~47~~, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g. --